



Office of Science and
Technology Policy



United States
Trade Representative

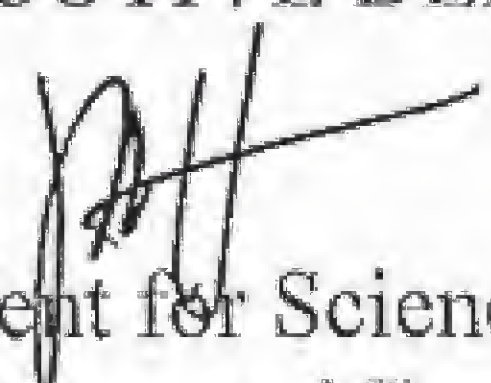


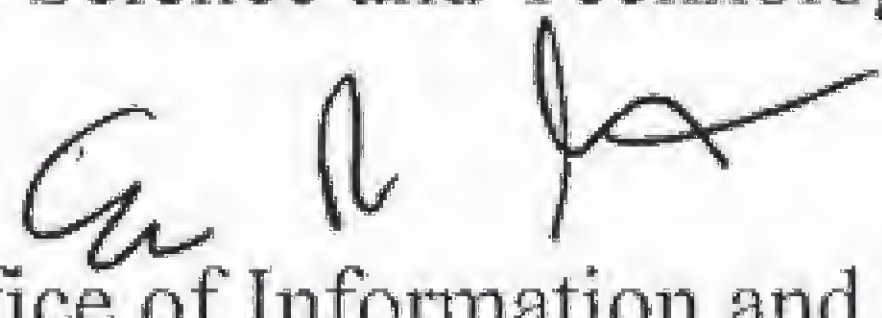
Administrator
Office of Information and
Regulatory Affairs


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MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM:

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SUBJECT:

Principles for Regulation and Oversight of Emerging
Technologies

Innovation with respect to emerging technologies -- such as nanotechnology, synthetic biology, and genetic engineering, among others -- requires not only coordinated research and development but also appropriate and balanced oversight. The White House Emerging Technologies Interagency Policy Coordination Committee (ETIPC) has developed the following broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies at the agency level.

We share a fundamental desire for regulation and oversight that ensure the fulfillment of legitimate objectives such as the protection of safety, health, and the environment. Regulation and oversight should avoid unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers.

To advance these goals, the following principles, consistent with Executive Order 13563 and discussed and approved by the ETIPC, should be respected to the extent permitted by law:

Scientific Integrity: Federal regulation and oversight of emerging technologies should be based on the best available scientific evidence. Adequate information should be sought and developed, and new knowledge should be taken into account when it becomes

available. To the extent feasible, purely scientific judgments should be separated from judgments of policy.

Public Participation: To the extent feasible and subject to valid constraints (involving, for example, national security and confidential business information), relevant information should be developed with ample opportunities for stakeholder involvement and public participation. Public participation is important for promoting accountability, for improving decisions, for increasing trust, and for ensuring that officials have access to widely dispersed information.

Communication: The Federal Government should actively communicate information to the public regarding the potential benefits and risks associated with new technologies.

Benefits and costs: Federal regulation and oversight of emerging technologies should be based on an awareness of the potential benefits and the potential costs of such regulation and oversight, including recognition of the role of limited information and risk in decision making.

Flexibility: To the extent practicable, Federal regulation and oversight should provide sufficient flexibility to accommodate new evidence and learning and to take into account the evolving nature of information related to emerging technologies and their applications.

Risk Assessment and Risk Management: Risk assessment should be distinguished from risk management. The Federal Government should strive to reach an appropriate level of consistency in risk assessment and risk management across various agencies and offices and across various technologies. Federally mandated risk management actions should be appropriate to, and commensurate with, the degree of risk identified in an assessment.

Coordination: Federal agencies should seek to coordinate with one another, with state authorities, and with stakeholders to address the breadth of issues, including health and safety, economic, environmental, and ethical issues (where applicable) associated with the commercialization of an emerging technology, in an effort to craft a coherent approach. There should be a clear recognition of the statutory limitations of each Federal and state agency and an effort to defer to appropriate entities when attempting to address the breadth of issues.

International Cooperation: The Federal Government should encourage coordinated and collaborative research across the international community. It should clearly communicate the regulatory approaches and understanding of the United States to other nations. It should promote informed choices and both sharing and development of relevant data, particularly with respect to the benefits and costs of regulation and oversight. The Federal Government should participate in the development of international standards, consistent with U.S. law and guidance (e.g., the National Technology Transfer and Advancement Act and OMB Circular A-119). When

appropriate, international approaches should be coordinated as far in advance as possible, to help ensure that such approaches are consistent with these principles.

Regulation: The Federal Government should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principles, to the extent permitted by law, when regulating emerging technologies:

- Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency;
- Regulations should be developed with a firm commitment to fair notice and to public participation;
- The benefits of regulation should justify the costs (to the extent permitted by law and recognizing the relevance of uncertainty and the limits of quantification and monetary equivalents);
- Where possible, regulatory approaches should promote innovation while also advancing regulatory objectives, such as protection of health, the environment, and safety;
- When no significant oversight issue based on a sufficiently distinguishing attribute of the technology or the relevant application can be identified, agencies should consider the option not to regulate;
- Where possible, regulatory approaches should be performance-based and provide predictability and flexibility in the face of fresh evidence and evolving information; and
- Regulatory approaches shall comply with established requirements and guidance such as the following:
 - Executive Order 13563 – Improving Regulation and Regulatory Review. Federal Register, Vol. 76, No. 14, Friday, January 21, 2011, 3821-3823, available at <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>;
 - Executive Order 12866 – Regulatory Planning and Review. Federal Register Vol. 58, No. 190, Monday, October 4, 1993, 51735-51744, available at <http://www.whitehouse.gov/omb/inforeg/eo12866.pdf>;
 - Information Quality Act (Sec. 515 of the Treasury and General Government Appropriations Act for FY 2001, Pub. L. No. 106-554); Information Quality Guidelines: OMB (2002) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of

Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002), available at <http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>;

- National Technology Transfer and Advancement Act of 1995 (“NTTAA”). Public Law 104-113, available at http://standards.gov/standards_gov/nttaa.cfm;
- Office of Management and Budget (OMB) Circular A-119, Transmittal Memorandum, Federal Participation in the Development and Use of Voluntary Standards (02/10/1998), available at <http://www.whitehouse.gov/omb/circulars/a119/a119.html>;
- OMB Final Information Quality Bulletin for Peer Review (December 16, 2004), available at <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>;
- OMB Bulletin No. 07-02 (M-07-07), Issuance of OMB's "Final Bulletin for Agency Good Guidance Practices" (January 18, 2007), available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>;
- OMB/OSTP Memorandum: M-07-24, Updated Principles for Risk Analysis (September 19, 2007), available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>;
- The Trade Agreements Act of 1979, as amended (Pub.L. 96-39, 93 Stat. 144, enacted July 26, 1979, codified at 19 U.S.C. ch.13 (19 U.S.C. § 2501–2581));
- “A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs” (September 2009), available at: http://www.whitehouse.gov/assets/documents/SEPT_20_Innovation_Whitepaper_FINAL.pdf; and
- Office of Information and Regulatory Affairs, Disclosure and Information As Regulatory Tools (June 18, 2010), available at http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/disclosure_principles.pdf